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UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

UNITED STATES OF AMERICA)
)
 v.) No. 23-cr-69-TSM-01/02
)
 CENTERA BIOSCIENCE, d/b/a)
 NOOTROPICS DEPOT)

PLEA AGREEMENT

Pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, the United States of America by its attorney, Jane E. Young, United States Attorney for the District of New Hampshire, and the defendant, Centera Bioscience, and the defendant's attorney, George Karavetsos, Esquire, enter into the following Plea Agreement:

1. **The Plea and The Offense.**

The defendant agrees to plead guilty to an Information charging it with the Introduction of a Misbranded Drug into Interstate Commerce, in violation of 21 U.S.C. § 331(a).

In exchange for the defendant's guilty plea, the United States agrees to the sentencing stipulations identified in Section 6 of this agreement.

2. **The Statute and Elements of the Offense.**

Title 21, United States Code, Section 331(a) provides, in pertinent part:

The following acts and the causing thereof are prohibited:

The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

21 U.S.C. § 331(a).

The defendant understands that the offense has the following elements, each of which the United States would be required to prove beyond a reasonable doubt at trial:

First, that the defendant introduced, or caused the introduction of, a drug into interstate commerce; and

Second, that the drug was adulterated or misbranded.

A violation of 21 U.S.C. § 331(a) is a strict liability offense. The United States does not have to prove that the defendant acted knowingly or intentionally.

See 21 U.S.C. § 331(a).

3. Offense Conduct.

The defendant stipulates and agrees that if this case proceeded to trial, the government would introduce evidence of the following facts, which would prove the elements of the offense beyond a reasonable doubt:

Centera Bioscience is a company based in Tempe, Arizona. Paul Eftang is the President and Chief Executive Officer of Centera Bioscience.

The Food and Drug Administration (“FDA”) is charged with enforcing the Food, Drug, and Cosmetic Act (“FDCA”). The FDCA defines drugs to include (1) “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man,” 21 U.S.C. § 321(g)(1)(B); and (2) “articles (other than food) intended to affect the structure or any function of the body of man,” 21 U.S.C. § 321(g)(1)(C).

Federal regulations define intended use to mean “the objective intent of the persons legally responsible for the labeling of [drugs] (or their representatives). The intent may be shown by such persons’ expressions, the design or composition of the [drugs], or by the circumstances surrounding the distribution of the [drugs]. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.” 21 C.F.R. § 201.128.

The FDCA defines “label” as “a display of written, printed, or graphic matter upon the immediate container of any article,” 21 U.S.C. § 321(k), and “labeling” as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article,” 21 U.S.C. § 321(m).

A drug is misbranded under the FDCA if its labeling fails to bear “adequate directions for use.” 21 U.S.C. § 352(f)(1). “Adequate directions for use” mean directions under which a layman can use a drug safely for the purposes for which it is intended. 21 C.F.R. § 201.5. A drug is misbranded under this provision if it fails to include, among other things, instructions concerning the quantity and frequency of dosage for each intended use. *Id.*

A drug is also misbranded under the FDCA if it is a prescription drug and it was dispensed without the prescription of a practitioner licensed by law to administer prescription drugs. 21 U.S.C. § 353(b)(1). A prescription drug includes any drug which, because of its toxicity or other potentiality for harmful effect, is not for use except under the supervision of a practitioner licensed by law to administer prescription drugs. 21 U.S.C. § 353(b)(1)(A).

Between April 2017 and December 2021, Centera Bioscience and Eftang sold multiple drugs, including tianeptine, phenibut, adrafinil, and racetam drugs. The racetam drugs included, but are not limited to, piracetam, aniracetam, coluracetam, and phenylpiracetam. Centera Bioscience and Eftang sold the drugs to consumers as nootropic compounds intended to affect the structure or function of the human body. These drugs are prescription drugs due to their toxicity and potential for harmful effect. Centera Bioscience and Eftang sold these prescription drugs without a valid prescription from a practitioner licensed to administer such drugs. Centera Bioscience and Eftang shipped these drugs, or caused the shipment of these drugs, to persons throughout the United States, including in New Hampshire. Centera Bioscience and Eftang also

marketed the drugs as nootropics through online platforms like Facebook and Google. Eftang and Centera Bioscience employees also regularly made representations about these drugs on a Reddit.com forum dedicated to Centera Bioscience products.

The labeling of the tianeptine, adrafinil, phenibut, and racetam drugs shipped did not bear adequate directions for use.

4. Penalties, Special Assessment and Restitution.

The defendant understands that the penalties for the offense are:

- A. A maximum fine of \$200,000 (18 U.S.C. § 3571(c)(5));
- B. A term of probation of not more than five years (18 U.S.C. § 3561(c)(2)); and
- C. A mandatory special assessment of \$125, \$125 for each count of conviction, at or before the time of sentencing (18 U.S.C. § 3013(a)(1)(B)(iii)).

5. Sentencing and Application of the Sentencing Guidelines.

The defendant understands that the Sentencing Reform Act of 1984 applies in this case and that the Court is required to consider the United States Sentencing Guidelines as advisory guidelines. The defendant further understands that it has no right to withdraw from this Plea Agreement if the applicable advisory guideline range or its sentence is other than it anticipated.

The defendant also understands that the United States and the United States Probation Office shall:

- A. Advise the Court of any additional, relevant facts that are presently known or may subsequently come to their attention;
- B. Respond to questions from the Court;
- C. Correct any inaccuracies in the pre-sentence report;
- D. Respond to any statements made by it or its counsel to a probation officer or to the Court.

The defendant understands that the United States and the Probation Office may address the Court with respect to an appropriate sentence to be imposed in this case.

The defendant acknowledges that any estimate of the probable sentence or the probable sentencing range under the advisory Sentencing Guidelines that it may have received from any source is only a prediction and not a promise as to the actual sentencing range under the advisory Sentencing Guidelines that the Court will adopt.

6. Sentencing Stipulations and Agreements.

Pursuant to Fed. R. Crim. 11(c)(1)(C), the United States and the defendant stipulate and agree that the following are an appropriate disposition of this case:

- (a) A term of three years of probation;
- (b) The conditions of probation shall also include the recommended conditions for organizations in U.S.S.G. § 8D1.4 that the Court deems applicable;
- (c) A special assessment of \$125 per count, for a total of \$125;
- (d) The forfeiture provisions set forth in this plea agreement; and
- (e) That no fine shall be imposed.

The parties intend the above stipulations to be "binding" under Fed. R. Crim. P. 11(c)(1)(C). By using the word binding the parties mean that if the Court will not accept the plea agreement under Fed. R. Crim. P. 11(c)(3)(A), the plea agreement is null and void and the defendant will be allowed the opportunity to withdraw its guilty plea.

The parties are free to make recommendations with respect to the conditions of probation and any other penalties, requirements, and conditions of sentencing as each party may deem lawful and appropriate, unless such recommendations are inconsistent with the terms of this Plea

Agreement.

7. Forfeiture

The defendant agrees to immediately and voluntarily forfeit to the United States its interest, if any, in any and all property subject to forfeiture pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c) as a result of its guilty plea, including, but not limited to all drugs seized by Customs and Border Protection and by FDA's Office of Criminal Investigations.

The defendant also agrees to the entry of a criminal forfeiture money judgment, pursuant to Fed. R. Crim. P. 32.2(b)(1), in the amount of \$2.4 million. The money judgment represents a fair estimate of the value of the misbranded tianeptine sold by the defendant, in violation of 21 U.S.C. § 331 and subject to seizure under 21 U.S.C. § 334.

The defendant agrees to cooperate fully in the forfeiture of the property to be forfeited. The defendant agrees to execute all documents necessary to effect forfeiture. The defendant further agrees to fully cooperate and testify truthfully on behalf of the United States in any legal action necessary to perfect the United States' interest, including but not limited to any ancillary hearing in this criminal action or in any civil litigation related to perfecting the United States' interest in the forfeited property.

The defendant understands and agree that forfeiture of this property is proportionate to the degree and nature of the offense committed by it. The defendant freely and knowingly waives all constitutional and statutory challenges in any manner (including direct appeal or any other means) to any forfeiture carried out in accordance with this Plea Agreement on any grounds, including that the forfeiture constitutes an excessive fine or punishment. The defendant further understands and agrees that this forfeiture is separate and distinct from, and is not in the nature of, or in lieu of, any penalty that may be imposed by the Court.

The defendant hereby releases and forever discharges the United States, its officers, agents, servants and employees, its heirs, successors, or assigns, from any and all actions, causes of action, suits, proceedings, debts, dues, contracts, judgments, damages, claims, and/or demands whatsoever in law or equity which it ever had, now have, or may have in the future in connection with the seizure, detention, and forfeiture of the described assets.

8. Waiver of Trial Rights and Consequences of Plea.

The defendant understands that it has the right to be represented by an attorney at every stage of the proceeding and, if necessary, one will be appointed to represent it. The defendant also understands that it has the right:

- A. To plead not guilty or to maintain that plea if it has already been made;
- B. To be tried by a jury and, at that trial, have the assistance of counsel;
- C. To confront and cross-examine witnesses; and
- D. To compulsory process for the attendance of witnesses to testify in its defense.

The defendant understands and agrees that by pleading guilty it waives and gives up the foregoing rights and that upon the Court's acceptance of its guilty plea, it will not be entitled to a trial.

The defendant understands that if it pleads guilty, the Court may ask its agent or agents questions about the offense, and if its agent or agents answer those questions falsely under oath, on the record, and in the presence of counsel, those false statements will be used against it in a prosecution for perjury or making false statements.

9. Acknowledgment of Guilt; Voluntariness of Plea.

The defendant understands and acknowledges that it:

- A. Is entering into this Plea Agreement and is pleading guilty freely and voluntarily

because it is guilty;

- B. Is entering into this Plea Agreement without reliance upon any promise or benefit of any kind except as set forth in this Plea Agreement or revealed to the Court;
- C. Is entering into this Plea Agreement without threats, force, intimidation, or coercion;
- D. Understands the nature of the offense to which it is pleading guilty, including the penalties provided by law; and
- E. Is completely satisfied with the representation and advice received from its undersigned attorney.

10. Scope of Agreement.

The defendant acknowledges and understands that this Plea Agreement binds only the undersigned parties and cannot bind any other non-party federal, state or local authority. The defendant also acknowledges that no representations have been made to it about any civil or administrative consequences that may result from its guilty plea. The defendant understands such matters are solely within the discretion of the specific non-party government agency involved. The defendant further acknowledges that this Plea Agreement has been reached without regard to any civil tax matters that may be pending or which may arise involving the defendant.

11. Satisfaction of Federal Criminal Liability; Breach.

The defendant's guilty plea, if accepted by the Court, will satisfy its federal criminal liability in the District of New Hampshire arising from its participation in the conduct that forms the basis of the information in this case.

The defendant understands and agrees that, if after entering this Agreement, it fails specifically to perform or fulfill completely each one of its obligations under this Agreement, fails to appear for sentencing, or engages in any criminal activity prior to sentencing, it will have breached this Agreement.

The defendant understands and agrees that, should the defendant's guilty plea be accepted, the defendant will deposit \$2,400,125 (representing the stipulated \$2,400,000 money judgment and \$125 special assessment) with the Court no later than 14 days before the scheduled sentencing date, which the Court will accept and hold pursuant to 28 U.S.C. § 2041. Failure to deposit these funds in full 14 days prior to sentencing may, in the sole discretion of the United States, be deemed a material breach of this Agreement.

If the United States, in its sole discretion, and acting in good faith, determines that the defendant committed or attempted to commit any further crimes, failed to appear for sentencing, or has otherwise violated any provision of this Agreement, the United States will be released from its obligations under this Agreement, including, but not limited to, any agreement it made to forbear prosecution of other crimes, or recommend a specific sentence or a sentence within a specified range. The defendant also understands that it may not use its breach of this Agreement as a reason to withdraw its guilty plea or as a basis to be released from its guilty plea.

12. Waivers.

A. Appeal.

The defendant understands that it has the right to challenge its guilty plea and/or sentence on direct appeal. By entering into this Plea Agreement the defendant knowingly and voluntarily waives its right to challenge on direct appeal:

1. Its guilty plea and any other aspect of its conviction, including, but not limited to, adverse rulings on pretrial suppression motion(s), other adverse dispositions of pretrial motions or issues, or claims challenging the constitutionality of the statute of conviction; and
2. The sentence imposed by the Court.

The defendant's waiver of its rights does not operate to waive an appeal based upon new legal principles enunciated in Supreme Court or First Circuit case law after the date of this Plea

Agreement that have retroactive effect; or on the ground of ineffective assistance of counsel.

B. Collateral Review

The defendant understands that it may have the right to challenge its guilty plea and/or sentence on collateral review, e.g., a motion pursuant to 28 U.S.C. §§ 2241 or 2255. By entering into this Plea Agreement, the defendant knowingly and voluntarily waives its right to collaterally challenge:

1. His guilty plea, except as provided below, and any other aspect of its conviction, including, but not limited to, adverse rulings on pretrial suppression motion(s) or any other adverse disposition of pretrial motions or issues, or claims challenging the constitutionality of the statute of conviction; and
2. The sentence imposed by the Court.

The defendant's waiver of its right to collateral review does not operate to waive a collateral challenge to its guilty plea on the ground that it was involuntary or unknowing, or on the ground of ineffective assistance of counsel. The defendant's waiver of its right to collateral review also does not operate to waive a collateral challenge based on new legal principles enunciated by in Supreme Court or First Circuit case law decided after the date of this Plea Agreement that have retroactive effect.

C. Freedom of Information and Privacy Acts

The defendant hereby waives all rights, whether asserted directly or through a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of the case(s) underlying this Plea Agreement, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. §552, or the Privacy Act of 1974, 5 U.S.C. §522a.

D. Appeal by the Government

Nothing in this Plea Agreement shall operate to waive the rights or obligations of the Government pursuant 18 U.S.C. § 3742(b) to pursue an appeal as authorized by law.

13. No Other Promises.

The defendant acknowledges that no other promises, agreements, or conditions have been entered into other than those set forth in this Plea Agreement or revealed to the Court, and none will be entered into unless set forth in writing, signed by all parties, and submitted to the Court.

14. Final Binding Agreement.

None of the terms of this Plea Agreement shall be binding on the United States until this Plea Agreement is signed by the defendant and the defendant's attorney and until it is signed by the United States Attorney for the District of New Hampshire, or an Assistant United States Attorney.

15. Agreement Provisions Not Severable.

The United States and the defendant understand and agree that if any provision of this Plea Agreement is deemed invalid or unenforceable, then the entire Plea Agreement is null and void and no part of it may be enforced.

JANE E. YOUNG
United States Attorney

08/15/2023
Date: _____

By:

Alexander Chen
Alexander S. Chen
Assistant United States Attorney
MA Bar Association #698458
53 Pleasant St., 4th Floor
Concord, NH 03301
Alexander.chen@usdoj.gov

I, Paul Eftang, the President and CEO of Centera Bioscience, d/b/a Nootropics Depot, the defendant, and empowered to bind Centera Bioscience in the matter, have read this 12-page Plea Agreement. I fully understand and, on behalf of Centera Bioscience, accept the terms thereof.

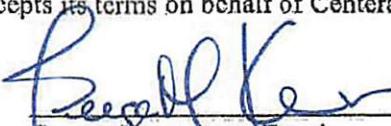
Date: 08/15/23



Paul Eftang
President and CEO of Centera Bioscience,
Defendant

I have reviewed and explained this 12-page Plea Agreement with Paul Eftang, President and CEO of Centera Bioscience, who is empowered to bind Centera Bioscience, the defendant, and he has advised me that he understands and accepts its terms on behalf of Centera Bioscience.

Date: 8/15/2023



George Karavetsos, Esquire
Attorney for Centera Bioscience